

DEC - 5 1997

Original 510(k)
Steri-Oss 3.25 mm Replace (Hydroxyapatite-Coated) Dental Implant

K973423
Section 6

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.
Submitter's Address: 22895 Eastpark Drive
Yorba Linda, CA 92887
USA
Contact's Name: Jeff Hausheer, Ph.D.
Contact's Telephone: 714-282-4800, extension 3815
Date Prepared: September 1997

Device Name:

Common Name: Prosthetic Dental Implant
Trade Name: Steri-Oss 3.25 mm Replace (Hydroxyapatite-Coated)
Dental Implant
Classification Name: Endosseous dental implant

Predicate Device:

Substantial equivalence is claimed to Steri-Oss' (Hydroxyapatite-coated) Replace Implants and to Steri-Oss' (3.25 mm diameter) Titanium Plasma Sprayed Cylindrical Implant (K911592).

Section 6
510(k) Summary

Device Description:

How The Device Functions:

This device is designed to serve as support for prosthetic devices to restore patient chewing function.

Scientific Concepts:

Natural dentition is composed of a root (subgingival) and a crown (supragingival). Endosseous dental implant designs in existence are intended to mimic this structure to aid the patient in restoring natural masticatory function. The subject implant is designed to serve as the root of the artificial tooth and the abutment/prosthesis is designed to serve as the crown. The healing screw and healing abutment are intermediary devices which serve to permit satisfactory completion of the implant healing/restoration process.

Device Characteristics:

This implant is 3.25 mm in diameter, 10 to 16 mm in length, and is fabricated from titanium alloy. They are threaded and have a superior external hex. The threaded portion of the implant body has a 50 micron thick plasma sprayed hydroxyapatite coating, and the surface of the external hex is anodized magenta in color.

Original 510(k)
Steri-Oss 3.25 mm Replace (Hydroxyapatite-Coated) Dental Implant

Section 6

510(k) Summary

Intended Use:

The intended use for this device is to serve as support for prosthetic devices to restore patient chewing functions.

Comparison to Predicate:

The following table provides a comparison of the principle technological characteristics of the 3.25mm Replace (Hydroxyapatite-Coated) Implant and the predicate.

Comparison to Predicates:

Specification/ Characteristic	Predicate: Steri-Oss Replace Implant	New Product: Steri-Oss 3.25 mm Replace (Hydroxyapatite-Coated) Dental Implant
Material	Titanium	Same
Surface Characteristics	Color-coded hex; hydroxyapatite coating on threaded portion of body	Same
Sterility	Sterile	Same

A second predicate, Steri-Oss' 3.25 mm titanium plasma sprayed cylindrical implant, is presented for the 3.25 mm diameter.

Performance Data:

Not applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 1997

Jeff Hausheer, Ph.D.
Regulatory Affairs Specialist
Steri-Oss, Incorporated
22895 East Park Drive
Yorba Linda, California 92687

Re: K973423
Trade Name: Steri-Oss 3.25mm Replace (Hydroxyapatite-
Coated) Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: September 8, 1997
Received: September 10, 1997

Dear Dr. Hausheer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

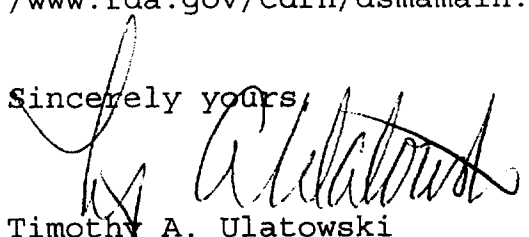
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Original 510(k)
Steri-Oss 3.25 mm Replace (Hydroxyapatite-Coated) Dental Implant

Section 9

Indications for Use

Page 1 of 1

510(k) Number (if known): _____

Device Name: 3.25 mm Replace (Hydroxyapatite-Coated) Dental Implant

Indications For Use: The intended use for this device is to serve as support for prosthetic devices to restore patient chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

S. J. [Signature]
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972423

Prescription Use ☒ OR Over-The-Counter Use _____ (Per 21 CFR 801.109)

(Optional Format 1-2-96)

Steri-Oss Inc. - September 1997